IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

CHARLES HENDERSON,

Plaintiff,

v. CIVIL ACTION FILE
NO. 4:11-CV-0060-HLM

SUN PHARMACEUTICALS INDUSTRIES, LTD, SUN GLOBAL, INC., CARACO PHARMACEUTICAL LABORATORIES, LTD, HOSPIRA INC., HOSPIRA WORLDWIDE, INC., UDL LABORATORIES, INC., MYLAN INC. f/k/a MYLAN LABORATORIES, INC., MYLAN BERTEK PHARMACEUTICALS INC., MYLAN PHARMACEUTICALS, INC.,

Defendants.

ORDER

This case is before the Court on Plaintiff's Motion to Amend Complaint [32], Plaintiff's Motion for Leave to File Supplemental Response [36], and the Motion to Dismiss

filed by Defendant Sun Pharmaceutical Industries, Ltd. ("Defendant Sun") [31].

I. Background

This is a products liability case arising out of Plaintiff's personal injuries allegedly resulting from his use of phenytoin and fosphenytoin. The Court detailed Plaintiff's allegations in its Order of June 9, 2011. (Order of June 9, 2011.) The Court fully incorporates those facts into this Order.

On June 9, 2011, the Court granted in part and denied in part Motions to Dismiss filed by Defendants Mylan Bertek Pharmaceutical, Inc. and Caraco Pharmaceutical Laboratories, Ltd. (Order of June 9, 2011.) The Court denied the Motions to Dismiss as to Plaintiff's failure to warn and joint and several liability claims. (Id.) The Court

granted the Motions to Dismiss without prejudice as to Plaintiffs' other claims and noted that the dismissal would be applicable to all Defendants. (Id.) After the Court's Order of June 9, 2011, Plaintiff's only remaining claims are for failure to warn and joint and several liability. (Order of June 9, 2011.)

On July 7, 2011 Defendant Sun filed a Motion to Dismiss. (Docket Entry No. 31.) Defendant Sun asserts that Pilva, Inc. v. Mensing, 2011 WL 2472790, 131 S. Ct. 2567 (June 23, 2011), establishes that Plaintiff's failure to warn claims against Defendants—generic manufacturers of phenytoin and fosphenytoin—are pre-empted by federal law. (Id.)[1] Because Plaintiff's only remaining substantive

[1]Defendant Sun initially argued that Plaintiff's Complaint should be dismissed on the basis of insufficient service of process. In it reply, however, Defendant Sun stated that, because Plaintiff produced a completed USM-94 form, Defendant "Sun withdraws

claim is for failure to warn, Defendant Sun contends that the Court should dismiss Plaintiff's Complaint in its entirety. (Id.)

On July 18, 2011 Plaintiff filed a Motion for Leave to File Amended Complaint ("Motion to Amend"). (Docket Entry No. 32.) Plaintiff's proposed Amended Complaint includes claims for design and/or manufacturing defect (Count I), negligence (Count II), joint and several liability (Count III), and punitive damages (Count IV). (Am. Compl.)

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this ground of its Motion to Dismiss." (Def. Sun's Reply Def. Sun's Mot. Dismiss at 6.) The Court therefore finds that Plaintiff provided sufficient service of process to Defendant Sun and denies Defendant Sun's Motion to Dismiss based on service of process.

Plaintiff, however, presumably failed to read Defendant Sun's reply and filed a Motion for Leave to File Supplemental Response "in order to establish that [Defendant Sun] was properly served under the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents." (Docket Entry No. 3601 at 2.) Because Defendant Sun is no longer pursuing their Motion to Dismiss for lack of service, the Court denies Plaintiff's Motion for Leave to File Supplemental Response as moot.

On July 21, 2011, Plaintiff filed a response to Defendant Sun's Motion to Dismiss. (Docket Entry No. 33.) Plaintiff asserts that, because he filed an amended complaint, the Court should deny Defendant Sun's Motion to Dismiss as moot. (Pl.'s Resp. Def. Sun Mot. Dismiss at 2.)

On August 2, 2011, Defendants Sun Pharmaceutical Industries, Inc. and Caraco Pharmaceutical Laboratories, Ltd. (the "Sun Defendants")[2] filed a response to Plaintiff's Motion to Amend. (Docket Entry No. 34.) The Sun Defendants argue that the Court should deny Plaintiff's Motion to Amend because the proposed Amended Complaint does not address the failures of the original Complaint, and amendment would therefore be futile. (Id.) On August 16, 2011, Plaintiff filed a Motion for Leave to

[2]Defendant Caraco is a subsidiary of Defendant Sun.

File Supplemental Response to Defendant Sun's Motion to Dismiss. (Docket Entry No. 36.)[3] The time period for Plaintiff to file a reply in support of his Motion to Amend has expired. Consequently, the briefing processes for those Motions are now complete, and the Court finds that the Motions are ripe for resolution.

The Court first evaluates Plaintiff's Motion to Amend and then analyzes the Sun Defendants' Motion to Dismiss.

II. Motion to Amend

A. Rule 15

The decision whether to grant leave to amend a pleading is committed to the sound discretion of the trial court. Southern Grouts & Mortars, Inc. v. 3M Co., 575 F.3d

[3]The Court finds that, given the outcome of the case, it is unnecessary for the parties to file responsive briefs to Plaintiff's Motion for Leave to File Supplemental Response Brief. The Court has reviewed Plaintiff's proposed response.

1235, 1239 (11th Cir. 2009). However, Federal Rule of Civil Procedure 15(a)(2), which provides that "the court should freely give leave [to amend] when justice so requires," drastically circumscribes the court's discretion to deny a motion to amend. Fed. R. Civ. P. 15(a)(2); Fla. Evergreen Foliage v. E.I. DuPont de Nemours & Co., 470 F.3d 1036, 1041 (11th Cir. 2006) (per curiam). A court thus may deny a motion to amend only if certain circumstances exist, including: (1) undue delay; (2) bad faith or dilatory motive; (3) repeated failure to cure deficiencies by amendments previously allowed; (4) undue prejudice to the opposing party; or (5) futility of the amendment. Equity Lifestyle Props., Inc. v. Fla. Mowing & Landscape Serv., Inc., 556 F.3d 1232, 1241 (11th Cir. 2009).

B. Standard Governing a Motion to Dismiss

Federal Rule of Civil Procedure 12(b)(6) allows the Court to dismiss a complaint, or portions of a complaint, for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss, the Court must take the allegations of the complaint as true, and must construe those allegations in the light most favorable to the plaintiff. Rivell v. Private Health Care Sys., Inc., 520 F.3d 1308, 1309 (11th Cir. 2008).

Although a court is required to accept well-pleaded facts as true when evaluating a motion to dismiss, it is not required to accept the plaintiff's legal conclusions. Sinaltrainal v. Coca-Cola Co., 578 F.3d 1252, 1260 (11th Cir. 2009) (citing Ashcroft v. Iqbal, 556 U.S. ---, ---, 129 S.

Ct. 1937, 1949 (2009)). When evaluating the sufficiency of a plaintiff's complaint, the court makes reasonable inferences in favor of the plaintiff, but is not required to draw the plaintiff's inference. Id. (quoting Aldana v. Del Monte Fresh Produce, N.A., Inc., 416 F.3d 1242, 1248 (11th Cir. 2005)). Similarly, the Court does not accept as true "'unwarranted deductions of fact'" or legal conclusions contained in a complaint. Id. (quoting Aldana, 416 F.3d at 1248).

The Court may dismiss a complaint "if the facts as pled do not state a claim for relief that is plausible on its face." Sinaltrainal, 578 F.3d at 1260. In Bell Atlantic Corporation v. Twombly, 550 U.S. 544 (2007), the Supreme Court observed that a complaint "requires more than labels and conclusions, and a formulaic recitation of the elements of a

cause of action will not do." 500 U.S. at 555. Although factual allegations in a complaint need not be detailed, those allegations "must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Id. Moreover, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 129 S. Ct. at 1949. The mere possibility that the defendant might have acted unlawfully is not sufficient to allow a claim to survive a motion to dismiss. Id. Instead, the well-pleaded allegations of the complaint must move the claim "across the line from conceivable to plausible." Twombly, 550 U.S. at 570.

Finally, the Court's consideration of a motion to dismiss is generally limited to the face of the complaint itself; however, "[t]he Eleventh Circuit has held that, when considering a 12(b)(6) motion to dismiss, a court may take judicial notice of the public record, without converting the motion to one for summary judgment, because such documents are capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Davis v. Williams Commc'ns, Inc., 258 F. Supp. 2d 1348, 1352 (N.D. Ga. 2003) (citing Bryant v. Avado Brands Inc., 187 F.3d 1271, 1279-80 (11th Cir. 1999)). Therefore, when addressing a motion to dismiss, the Court "may also consider any attachments to the complaint, matters of public record, orders, and items appearing in the record." Clark v. Bibb County Bd. of Educ.,

174 F. Supp. 2d 1369, 1370 (M.D. Ga. 2001); see 5C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1364 (3d ed. 2004) (stating that "judicial notice may be taken of prior pleadings and proceedings . . . transcripts of prior court proceedings, and various documents that are matters of public record").

C. Analysis

Plaintiff's Amended Complaint contains fewer claims and some more detailed allegations. For the following reasons, however, the Court finds that Plaintiff's proposed Amended Complaint fails to state a claim, and that amendment would therefore be futile.

1. Strict Liability

In Count I, Plaintiff alleges strict liability—defective in design or manufacture—against Defendants Hospira and Sun.

O.C.G.A. § 51-1-11(b) states:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

O.C.G.A. § 51-1-11(b). To state a claim for strict liability, the plaintiff must show that (1) the defendant was manufacturer of the product; (2) the product, when sold, was not merchantable and reasonably suited to the use

intended, and (3) the product's defective condition proximately caused the plaintiff's injury. Chicago Hardware & Fixture Co. v. Letterman, 236 Ga. App. 21, 23, 510 S.E.2d 875, 877 (1999).

In the Court's Order of June 9, 2011, the Court found that Plaintiff's general, conclusory allegations were insufficient to state a manufacturing or design defect claim against Defendants. (Order of June 9, 2011 at 23.) For the following reasons, the Court finds that Plaintiff's Amended Complaint still fails to include sufficiently specific allegations to state a viable claim for strict liability, defective in design or manufacture.

Initially, the Court recognizes that the Amended Complaint includes two new sections purported to provide additional allegations specific to the Sun Defendants and

the Hospira Defendants. (Am. Compl. ¶¶ 72-95). Those additional allegations, however, fail to provide sufficient factual detail for Plaintiff's strict liability claims to survive a Motion to Dismiss.

First, Plaintiff alleges that Defendant Caraco, an affiliate of Defendant Sun, received a warning letter from the Food and Drug Administration ("FDA") "regarding reports of product failures at its pharmaceutical manufacturing facilities in Detroit, Michigan." (Am. Compl. ¶ 76.) Plaintiff alleges that the "FDA inspection of [Defendant Caraco's] manufacturing facilities . . . revealed serious and systematic manufacturing compliance problems with regard to the manufactured drug products." (Id. ¶ 78.) Plaintiff further contends that U.S. Marshals seized $20 million of products and raw material. (Id. ¶ 81.) Defendants argue that those

allegations are irrelevant to this case. According to Defendants, Defendant Caraco has never manufactured phenytoin and phenytoin was not included in the seized pharmaceuticals.

The Court finds that Plaintiff's additional allegations fail to demonstrate that Defendant Caraco was the manufacturer of phenytoin or that phenytoin included a design or manufacturing defect. First, although the documents Plaintiff includes in the Complaint indicate that the FDA identified manufacturing issues at Defendant Caraco's manufacturing facilities, none of the allegations are specific to phenytoin, and none of the allegations provide a causal link between any manufacturing or design defect and SJS/TEN or any other injury Plaintiff suffered. Second, the FDA documents provided by Defendants

indicate that Defendant Caraco did not manufacture phenytoin and fosphenytoin, and that those drugs were not among the drugs seized by the FDA. (See Defs.' Resp. Mot. Amend Exs. 1-2.)[4]

The specific allegations against Defendant Hospira also fail to demonstrate that Plaintiff's strict liability claim against Defend Hospira is plausible. First, although Plaintiff includes an FDA letter that specifically mentions manufacturing defects in fosphenytoin, Plaintiff provides no allegations of a link between those defects and SJS/TEN or

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[4]The Court is permitted to take judicial notice of documents made publicly available by a government entity. Daniels-Hall v. National Educ. Ass'n, 629 F.3d 992, 998-99 (9th Cir. 2010 (citing In re Amgen Inc. Sec. Litig., 544 F. Supp. 2d 1009, 1023-24 (C.D. Cal. 2008) (taking judicial notice of drug labels from FDA website)); see also Fellner v. Tri-Union Seafoods, LLC., No. 06–CV–0688, 2010 WL 1490927 (D.N.J. Apr. 13, 2010) (taking judicial notice of FDA documents and collecting cases establishing that judicial notice is proper for government documents).

any of Plaintiff's injuries. (Am. Compl. ¶ 88.) Second, although Plaintiff alleges that the inaccuracies on the labeling of Defendants' products "directly caused [Plaintiff] to develop a SCAR event," Plaintiff's Amended Complaint no longer includes a failure to warn claim, and, as discussed below, such state tort failure to warn claims are preempted by federal law.

The allegations listed under Count I also fail to address the defects of the original Complaint and do not state a claim for strict liability. Plaintiff still does not allege that any specific design or manufacturing defect proximately caused Plaintiff to develop SJS/TEN or any other injury. The proposed Amended Complaint does allege that the "[fosphenytoin] drug products contained impurities in the manufacturing process . . .", but Plaintiff does not specify

the impurities or allege how those impurities caused Plaintiff to develop SJS. (Am. Compl. ¶ 99(a).) Instead, Plaintiff merely states that "[as] a direct and proximate result of the design and manufacturing defects . . . Mr. Henderson suffered harm as alleged herein . . . ." (Id. ¶ 107.) Such general, conclusory allegations, devoid of any specific, factual content to support the legal conclusions are plainly insufficient under Iqbal. The Court therefore finds that Plaintiff's proposed Amended Complaint fails to state a plausible claim that phenytoin's defective condition proximately caused Plaintiff's injuries.

2. Negligence

In the Amended Complaint, Plaintiff alleges that "Defendants failed to exercise ordinary care in the manufacture, sale, marketing, quality assurance, quality

control, and distribution of the drugs at issue . . . ." (Am. Compl. ¶ 128.) Specifically, Plaintiff alleges that "Defendants failed to comply with the FDA post-marketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience." (Id. ¶ 129.) Plaintiff lists fifteen "acts and omissions" that allegedly demonstrate Defendants' negligence. (Id. ¶ 130.)

Under Georgia law, a plaintiff asserting a negligence claim must prove the following elements: "(1) a legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risk of harm; (2) breach of this standard; (3) a legally attributable causal connection between the conduct and resulting injury; and, (4) some loss or damage flowing to the plaintiff's legally protected interest as a result of the alleged breach of the

legal duty." Estate of Thornton v. Unum Life Ins. Co. of Am., 445 F. Supp. 2d 1379, 1382 (N.D. Ga. 2006) (citing Berry v. Hamilton, 246 Ga. App. 608-09, 541 S.E.2d 428, 429-30 (2000)).

Defendants argue that Plaintiff has failed to establish a duty because there is no private right of action under the Federal Food Drug and Cosmetic Act ("FDCA") to enforce such post-marketing requirements. According to Defendants, because the FDA alone has the power to enforce the FDCA, such claims are preempted by federal law. Further, according to Defendants, even if Plaintiff establishes that Defendants did breach their duty of care, Plaintiff's proposed Amended Complaint remains futile because it fails to link Plaintiff's alleged injury to this supposed breach.

The Court finds that Plaintiff's Amended Complaint fails to identify any causal connection between any specific act or omission, including Defendants' failure to properly report, and SJS/TEN or any injury suffered by Plaintiff. Instead, after listing fifteen acts or omissions, Plaintiff states: "As a result of Defendants' foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at greatly increased risk of serious and dangerous side effects including, inter alia, SJS/TEN . . . ." (Am. Compl. ¶ 132.) Plaintiff lists numerous duties, Defendants, acts or omissions, and injuries, but does not allege any relationship between a specific Defendant, a specific breach, and a specific injury. Such general, conclusory allegations are insufficient to state a claim under Iqbal. The Court therefore finds that Plaintiff's proposed Amended

Complaint fails to state a claim for negligence, and that allowing the amendment would consequently be futile.[5]

3. Joint and Several Liability/Punitive Damages

Counts III and IV are derivative claims requiring an underlying tort. As discussed above, Plaintiff's Amended Complaint fails to state a claim for strict liability or negligence. Plaintiff's joint and several liability and punitive

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[5]The Court does not determine whether there is a private right of action under the post-marketing requirement of the FDCA. Defendants cite Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341, 349 (2001), for the proposition that there is no right of action under the FDCA to enforce post-marketing reporting requirements. In Buckman, the Supreme Court held that state-law fraud-on-the-FDA claims were preempted by federal law in the context of medical devices. Because both cases involve inadequate disclosure to the FDA, there is dicta that may indicate that claims under § 314.80(c) should also be preempted. The Court, however, declines to decide that issue absent additional briefing. In any case, the Court finds that determining whether a private cause of action exists is unnecessary because Plaintiff fails to sufficiently allege causation, and Plaintiff's claim consequently fails.

damages claims consequently fail as a matter of law.

D. Summary

Plaintiff's proposed Amended Complaint fails to address the inadequacies of the original Complaint identified in the Court's Order of June 9, 2011. Specifically, Plaintiff fails to sufficiently allege a causal link between any design defect, manufacturing defect or negligent act and Plaintiff's injuries or development of SJS/TEN. The Court therefore finds that amendment would be futile and denies Plaintiff's Motion to Amend. The original pleadings therefore remain, and Defendant Sun's Motion to Dismiss is not rendered moot. See Brown v. West Valley Environmental Services, LLC, 2010 WL 5575327 at *5 (W.D.N.Y. Sept. 2, 2010) ("This Court, in striking the filed Amended Complaint and denying leave to file an

amendment, noted that defense motions to dismiss the original pleadings remain following the disposition of the proposed Amended Complaint.") (internal quotation omitted). The Court next evaluates Defendant Sun's Motion to Dismiss the original Complaint.

III. Motion to Dismiss

In its Motion to Dismiss, Defendant Sun asserts that Plaintiff's failure to warn claim against Defendants—generic manufacturers of phenytoin and fosphenytoin–are preempted by federal law. For the following reasons, the Court agrees and dismisses Plaintiff's failure to warn claims against all Defendants.

Mensing involved a state tort claim based on "certain drug manufacturers' alleged failure to provide adequate warning labels for generic metocopramide." Mensing, 121

S. Ct. at 2572. The Supreme Court found that, while state tort law requires manufacturers to safely label their products, federal law only requires generic manufacturers to make their warning labels identical to those provided by the brand manufacturer of the drug. Id. at 2577. The Court held that—because generic manufacturers cannot legally choose to independently strengthen their labeling—it is impossible for a generic manufacturer to comply with both federal and state law. Id. at 2578. The Court therefore found that federal law preempts state law tort claims attacking the sufficiency of the warning on a generic drug. Id. at 2578.

Defendant Sun argues that, after Mensing, Plaintiff's failure to warn claim is preempted by federal law. Defendant Sun contends that, under federal law, its labeling of

phenytoin is required to match the labeling of Dilantin in all respects, regardless of state law. Plaintiff's claim attacks the sufficiency of the warnings provided by Defendant Sun and other generic manufacturers under state law. According to Defendant Sun, this is precisely the type of claim that Mensing held was preempted by federal law.

Plaintiff argues that Mensing only preempted failure to warn claims premised on the theory that a generic company could unilaterally change its warning under a Change Being Effected Supplement under 21 C.F.R. 314.70(c)(6)(iii). Plaintiff explains that the Supreme Court stated that, the FDA "interprets the CBE regulation to allow changes to generic drug labels only when a generic manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." Mensing, 131 S. Ct. at

2566.

The Court finds that Mensing preempts Plaintiff's failure to warn claim against Defendant Sun. The FDA and the Supreme Court agree that a generic drug manufacturer can only change its label when it fails to match the warning on a brand name label. Plaintiff does not contend that Defendants' labeling is inconsistent with Dilantin's labeling. Rather, Plaintiff claims that Defendants' labeling is inadequate under state tort law. Defendant Sun correctly asserts that this is exactly the type of state tort failure to warn claim that the Mensing Court found was preempted by state law. The Court consequently finds that Plaintiff's state law failure to warn claim is preempted by federal law. The Court therefore grants Defendant Sun's Motion to Dismiss

as to Plaintiff's failure to warn claim.[6]

B. Joint and Several Liability

As discussed above, joint and several liability is a derivative claim that requires an underlying tort. The Court has dismissed all of Plaintiff's substantive tort claims against Defendants. The Court consequently dismisses Plaintiff's claim for joint and several liability.

IV. Summary

The Court finds that amendment would be futile and denies Plaintiff's Motion to Amend—only Plaintiff's original Complaint remains. The Court finds that Plaintiff's failure to

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[6]The Court dismisses Plaintiff's failure to warn claim as to all Defendants. Plaintiff only took phenytoin and fosphenytoin, generic versions of Dilantin. Plaintiff does not assert a failure to warn claim against the manufacturer of the brand name drug. Mensing establishes that federal law preempts state law failure to warn claims against manufacturers of generic drugs. Plaintiff's failure to warn claims consequently fail as a matter of law as to all Defendants.

warn claim is preempted by federal law and dismisses that claim as to all Defendants. Absent an underlying tort, Plaintiff's joint and several liability claim fails as a matter of law. In its Order of June 9, 2011, the Court dismissed Plaintiff's other claims as to all Defendants. (Order of June 9, 2011). The Court consequently finds that Plaintiff's Complaint fails to state a claim against any Defendant and dismisses Plaintiff's Complaint without prejudice.[7]

V. Conclusion

ACCORDINGLY, the Court **DENIES** Plaintiff's Motion to Amend [32], **DENIES** Plaintiff's Motion for Leave to File Supplemental Response [36], and **GRANTS** Defendant

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[7]Although the Court has already allowed Plaintiff one opportunity to amend its Complaint, at this time the Court cannot find that it would be impossible for Plaintiff to state a claim against any Defendant. The Court therefore dismisses this action without prejudice.

Sun's Motion to Dismiss [31]. The Court finds that Plaintiff's Complaint fails to state a claim against any Defendant, and **DISMISSES** Plaintiff's Complaint **WITHOUT PREJUDICE**.

The Court **DIRECTS** the Clerk to **CLOSE** this case.

IT IS SO ORDERED, this the 22 day of August, 2011.

UNITED STATES DISTRICT JUDGE